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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/502,066

10/27/2004

W Wayne Lautt

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23552 7590 08/04/2008  
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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

08/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/502,066	<b>Applicant(s)</b> LAUTT, W WAYNE	
	<b>Examiner</b> SHIRLEY V. GEMBEH	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,3,9,12-15,17-19,22-33 and 36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,9,12-15,17-19,22-33 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/29/08</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 4/29/08 is acknowledged and have been reviewed.

Claims 2-3, 9, 12-15, 17-19, 22-33 and 36 are pending.

Claims 2, 9, 12, 14, 17-19, 22-24 are amended.

### ***Response to Arguments***

The response filed on 4/29/08 presents remarks and arguments to the office action mailed on 10/29/07. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Objections is withdrawn based on the amendment to the claim.***

***Maintained Claim Rejections - 35 USC § 103***

Applicant argues that the claims require the acetylcholine esterase antagonist to be targeted to the liver, and that can be accomplished through the use of pharmaceutically acceptable liver-targeting substance.

Also, that the Thiele reference does not teach that neoeserin targets the liver but rather affects the vagus nerve at some position in the body, which then affects the liver. Applicant addresses the term vagotonic by submitting a dictionary meaning for the term. In summary, Applicant argues that Thiele does not teach targeting the liver with the claimed compound.

In response, this is not deemed persuasive because, no where in the claims does it require the drugs to be specifically formulated to target the liver as argued; the claims simply require a method of reducing insulin resistance by administering an effective amount of an acetylcholine esterase antagonist, wherein the acetylcholine esterase antagonist is targeted to the liver. Therefore as known to one skilled in the art, a property of an identical drug/compound would not change and would expect the drugs/compounds to function the same, i.e. target the liver. Also, as stated by Applicant the drug neoeserin (known as neostigmine) targets the liver via the vagus nerve, the claims do not call for any pathway to which the drug will target the liver. It is believed and as taught by the reference that the drug targets the liver via the vagus nerve. Same compositions must have the

same properties. The discovery of a new property, targeting the liver, does not impart patentability.

Careful consideration has been given to the remarks, but they are not persuasive for the above reasons. The rejection is maintained as in the last office action dated 10/29/07.

Claims 2-3, 9, 12-15, 17-19, 22-33 and 36 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Thiele et al., Thiele et al., (1957) "Decrease in urinary sugar in diabetes mellitus by vagotonic treatment with neoeserine", *Munch Med Wochenschr.*, Aug 23; 99(34): 1203-1206 (Applicants IDS) in view of American Diabetes Association 1998 as evident by drugdelivery.ca and <http://syndromex.stanford.edu/InsulinResistance.htm>.

Claims 14-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Thiele et al., Thiele et al., (1957) "Decrease in urinary sugar in diabetes mellitus by vagotonic treatment with neoeserine", *Munch Med Wochenschr.*, Aug 23;99(34): 1203-1206 (Applicants IDS) in view of American Diabetes Association 1998 as evident by drugdelivery.ca and <http://syndromex.stanford.edu/InsulinResistance.htm> as applied to claims 2, 5, 9-10, 12, 14-15, 17-19, 21, 25-29, 31-32, 43-45 above, and further in view of Dow US 6,194,454.

***Maintained Double Patenting***

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Applicant's request that the Double Patenting rejection be held in abeyance until an indication of allowable subject matter is noted but the rejection will be maintained in this Office Action and future Office Actions until withdrawn.

Claims 2-3, 9, 12-15, 17-19, 22-33 and 36 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1 –7,9, 11, 15 24, 32-46** of U.S. Patent Application No. **11/597,032**.

Although the conflicting claims are not identical, they are not patentably distinct from each other.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/SVG/  
7/31/08